



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

JUL -3 2002

Michael D. Alexander  
Sanofi Pharmaceuticals Inc.  
9 Great Valley Parkway  
Malvern PA 19355

Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,270,317

Dear Mr. Alexander:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 5,270,317 for a period of 194 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: <http://www.fda.gov/cder/orange/patdecl.pdf>.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: David T. Read  
Health Assessment Policy Staff  
Acting Director Health Assessment Policy Staff, CDER  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

RE: AVAPRO® (irbesartan)  
FDA Docket No.: 98E-0781

# UNITED STATES PATENT AND TRADEMARK OFFICE

## (12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 5,270,317  
(45) ISSUED : December 14, 1993  
(75) INVENTOR : Claude Bernhart, et al.  
(73) PATENT OWNER : Elf Sanofi  
(95) PRODUCT : AVAPRO® (irbesartan)

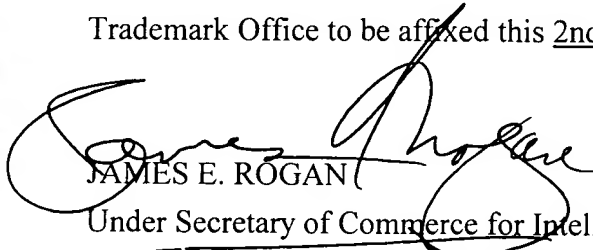
This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 5,270,317 based upon the regulatory review of the product AVAPRO® (irbesartan) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 194 days

from March 20, 2011, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 2nd day of July 2002.

  
JAMES E. ROGAN

Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office